K 130023

APR 0 3 2013

510(k) SUMMARY

December 31, 2012

Applicant:

NP Medical.
101 Union St
Clinton, MA 01501
Tel: +978 368-4514

Contact Person:

Luis J Maseda
General Manager

Trade Name: K100 Neutral Displacement Needle Free Connector

Common Name: Needleless IV connector

Classification Name: Intravascular Administration Set

Classification Panel: 80-General Hospital

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1.0 DEVICE SUMMARY

The K100 Neutral Displacement Needle Free Connector (K100) is a medical device designed for direct injection, intermittent infusion, continuous infusion, or aspiration without the need for sharps devices.

Classification Information

Table 1: Device Classification

Classification or descriptor	Name or designation
Trade Name	K100 Neutral Displacement Needle Free Connector
Common Name	Needleless IV connector
Classification Name	Intravascular Administration Set
Classification Panel	80-General Hospital
Product Code	FPA
Regulation Number	21 CFR 880.5440

2.0 INTENDED USE AND INDICATIONS FOR USE

Indications for Use

The K100 Neutral Displacement Connector is a single patient use, sterile, non-pyrogenic device for needleless access to the IV line and/or IV catheter during IV therapy. The K100 connector can be used for direct injection, intermittent infusion, continuous infusion, or aspiration.

3.0 DEVICE DESCRIPTIONS

The K100 Neutral Displacement Needleless Connector is a sterile, single patient use, swabable, normally closed, luer-activated, valved connector.

The K100 valve is comprised of a:

- housing (inlet and outlet),
- a fluid channel,
- a translating member (or lower gland) secured to a longitudinal wall of the housing and bounding a variable volume region of the fluid channel,
- a post having a lumen terminating at a distal head of the post and biased in the proximal direction by the lower gland when in the closed mode, and

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- an upper seal having a sealing ring and secured to the longitudinal wall of the housing, the sealing ring contacting the distal head of the post when in the closed mode to prevent flow through the fluid channel,
- Moving components within the assembly are lubricated with silicone oil.

4.0 PREDICATE DEVICES

The K100 Neutral Displacement Needle Free Connector is substantially equivalent to the following predicate products.

Table 2: Predicate Device

Product	Cleared Predicate Product k number
NP Medical Capless Needleless Luer Connector	K973916

5.0 COMPARISON OF DEVICE UNDER REVIEW AND ITS PREDICATES

Table 3: Comparison of proposed new device and its predicates.

Comparison Element - Similarities	(Subject devices) K100 Neutral Displacement Needle Free Connector	(Predicate device) Capless Needleless Luer Connector
510k holder	NP Medical, Inc	NP Medical, Inc.
Manufacturer	NP Medical, Inc.	NP Medical, Inc.
Indication for/ Intended Use	The K100 Neutral Displacement Connector is a single patient use, sterile, non-pyrogenic device for needleless access to the IV line and/or IV catheter during IV therapy. The K100 connector can be used for direct injection, intermittent infusion, continuous infusion, or aspiration.	The Capless Luer Activated Valve, incorporating a luer activated valve, is intended for use in facilitating needleless fluid delivery and may be swabbed with antiseptic just prior to use, thereby eliminating the need for capping between uses.
Displacement Type	Neutral	Negative
Luer connector	ISO luer	ISO luer
Multiple Activations	96 intermittent	96 intermittent
Indwell	96 hours	96 hours
Chemical Compatibility	Lipids, Alcohol, CHG	Lipids, Alcohol

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Table 3: Comparison of proposed new device and its predicates.

Comparison Element - Similarities	(Subject devices) K100 Neutral Displacement Needle Free Connector	(Predicate device) Capless Needleless Luer Connector
Pressure Rating	325 psi	> 60 psi
Priming Volume	0.12 mL	0.25 mL
Microbial ingress Test	Pass	Pass
Sterile	Yes	Yes
Packaging Type	Blister	Blister
Materials	PC/Silicone (no latex or DEHP)	PC/Silicone (no latex or DEHP)

As demonstrated in Table 3, there are equivalent features and functional uses between the devices. Materials are tested to the latest ISO 10993 standards. Differences are in displacement, maximum pressure, and priming volume. These differences do not introduce any new safety or efficacy risks to the patient.

6.0 PERFORMANCE TESTING – BENCH

NP Medical has conducted risk analyses and design verification/validation tests based on the result of these analyses.

All test results meet the acceptance criteria, and support that the devices are appropriately designed for their intended use. The following bench tests were conducted to evaluate the design on the functional performance of the K100 Neutral Displacement Needle Free Connector.

Verification and Validation Testing conducted by NP Medical .All tests met acceptance criteria.

Table 4: K100 Verification and Validation Testing

Test Name
Air Bolus and Bubble Free Priming
Repeat Insertion
Blood Flushing Evaluation
Bolus Back Pressure
Docking Stability
Flow Rate
Fluid Displacement

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Test Name
Gland Height Determination
Hydraulic Burst Leak
ISO 594 Test Methods
Lipid Resistance
Priming Volume
Residual Volume
Stress Resistance to Swabbing Chemicals (IPA and CHG).
Torque Testing

In addition to the Bench testing, NP Medical has successfully conducted Microbial Ingress testing, Sterilization Validation and Packaging/Shelf Life Validation.

7.0 CONCLUSION

7.1 The K100 Neutral Displacement Needle Free Connector is substantially equivalent to the identified predicate system based on the indication for use, design features, operating principles, performance tests and material composition.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2013

Mr. Luis J Maseda
General Manager
NP Medical Incorporated
101 Union Street
CLINTON MA 01501

Re: K130023
Trade/Device Name: K100 Neutral Displacement Needle Free Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 31, 2012
Received: January 3, 2013

Dear Mr. Maseda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

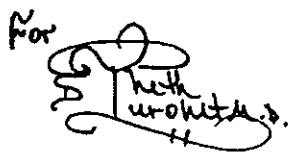
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K130023

Device Name: K100 Neutral Displacement Needle Free Connector

Indication for Use:

The K100 Neutral Displacement Needle Free Connector is a single patient use device for needleless access to the IV line and/or IV catheter during IV therapy. The K100 connector can be used for direct injection, intermittent infusion, continuous infusion, or aspiration.

Prescription Use ___x___ (21 CFR Part 801 Subpart D) and/or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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Division Sign-Off
Office of Device Evaluation

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